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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,990	01/22/2001	Jerome Besse	P66226US0	4037

136 7590 03/26/2003

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EXAMINER

DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 03/26/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/764,990

Applicant(s)

BESSE JEROME ET AL.

Examiner

Liliana Di Nola-Baron

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-28,30 and 31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-28,30 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of Applicant's request for continued examination, filed on February 21, 2003, and entry of Applicant's amendment, filed on December 23, 2002, are acknowledged.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 20-28, 30 and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification, while being enabling for treating radiomucositis and chemomucositis, does not reasonably provide enablement for "preventing" radiomucositis and chemomucositis.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

Art Unit: 1615

(1) The nature of the invention:

The invention is directed to a composition comprising flavonoids and isoflavonoids and a vehicle, which is liquid at room temperature and gels at the temperature of the mucous membrane and a method for the prevention and treatment of radiomucositis and chemomucositis comprising administering said composition to the mucous membrane.

(2) The state of the prior art

The prior art discloses compositions comprising flavonoids for treating damage to the mucous membranes caused by radiation. However, the compositions disclosed by the prior art are in the form of emulsions having thick consistence, which become more fluid at body temperature, rather than thicken into gels, as claimed in the instant application.

(3) The relative skill of those in the art

The relative skill of the those in the art is high.

(4) The predictability or unpredictability of the art

The unpredictability of the flavonoid art is very high. The true fact of the state of the art in flavonoid chemistry is expressed succinctly in U.S. Patent 6,316,012 (See col. 1 in particular). "It is known that some antioxidants are capable of conferring a protection against the skin damage caused by radiation...The applicant has discovered that, surprisingly, certain combinations had the property of inhibiting the formation of ODC, while the constituents of the combination, when used alone, had no effect or even caused an increase in the induction of

Art Unit: 1615

ODC." In the instant invention the predictability is very low and consequently there is the need for a higher level of directions and guidance by Applicant.

(5) The breadth of the claims

The claims are very broad. The flavonoids are not defined in the generic claims. The limiting claims that limit the nature of the flavonoids still claim five categories of flavonoids.

(6) The amount of direction or guidance presented

The amount of direction and guidance provided by Applicant is limited to treatment of radiomucositis and chemomucositis. There is no evidence in the specification that established correlation between the experiments and the claimed utility.

(7) The presence or absence of working examples

The working examples present no data on the effect of the compositions of the invention on the prevention of radiomucositis and chemomucositis.

(8) The quantity of experimentation necessary

The effect of the compositions of the invention on the possible development of radiomucositis and chemomucositis cannot be predicted a priori but must be determined from the case to case by painstaking experimental study in vivo. When the above factors are weighed together, one of ordinary skill in the art would be burdened with undue "painstaking

Art Unit: 1615

experimentation study" to determine a possible preventive effect of the compositions and methods claimed in the instant application.

Response to Arguments

3. Applicant's arguments, filed on December 23, 2002, have been fully considered and are persuasive, since the prior art discloses compositions in the form of emulsions having thick consistence, which become more fluid at body temperature, rather than thicken into gels, as claimed by Applicant. The 35 U.S.C. 103(a) rejection of claims 20-29 of the previous Office action has been withdrawn.

Conclusion

4. Claims 20-28, 30 and 31 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Art Unit: 1615

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

A handwritten signature in black ink, appearing to be 'SMB'.

March 20, 2003

A handwritten signature in black ink, appearing to be 'Thurman K. Page'.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600